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EXAMINER	
MARTIN, PAUL C	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/734,687	WECHTER ET AL.	
	Examiner	Art Unit	
	Paul C. Martin	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *12-29 and 31-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *04/15/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-33 are pending in this application.

Election/Restrictions

Applicant's election with traverse of Group I (Claims 1-11 and 30) in the reply filed on 05/26/06 is acknowledged. The traversal is on the ground(s) that the inventions found in Groups I-III are not patentably distinct from each other. This is not found persuasive because as stated in the original restriction requirement mailed 05/05/06, the different inventions are directed toward methods that are both physically and functionally distinct, such that the particulars of one group are not required for another.

Claims 12-29 and 31-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

The requirement is still deemed proper and is therefore made FINAL.

Specification

The abstract of the disclosure is objected to because Page 2, line 11 of the specification which states, "The approximate frequency of [cystic fibrosis] is 1 in 2000. The Examiner has found information that tends to indicate that about 1 in 3,000 Caucasians has CF (Genetics Home Reference, Lines 22-24). Thus, there is a discrepancy between what the information the Examiner has found and what is cited in the Specification. Applicant is asked to remedy this discrepancy to overcome this objection and to avoid confusion. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 and 30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detecting the ability of a compound to influence a) the binding of α-methylacyl-CoA racemase (AMACR) to a ligand, b) the expression of AMACR RNA or DNA, and the amount and location of AMACR and its byproducts, does not reasonably provide enablement for all possible interactions involving AMACR.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

At issue is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record.

In re Wands states that the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. The biological sciences are by nature an unpredictable art which is based upon experimentation, however one of skill in the art at the time of the invention would not by sufficiently informed by the instant disclosure as to the nature of all of the possible interactions involving the endogenous AMACR enzyme. The specification provides some guidance, but no working examples or reduction to practice of any screening process which characterizes a compounds influence on interactions involving AMACR.

However, the instant disclosure can not fully enable the entire scope of interactions involving the AMACR enzyme as this would any and every process by which AMACR plays any role, however cursory or minute. Based upon this reasoning, the Examiner concludes that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 6 recites the limitation "said ligand" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 5 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmitz *et al.* (1995).

Schmitz teaches a screening method for determining the ability of various acyl-CoAs to inhibit the racemization of the α-methylacyl CoA thioester [2-H^3]Pristanoyl-CoA by isolated and purified human α-methylacyl-CoA racemase, the various other CoAs acting as competitive inhibitors between the interaction of α-methylacyl-CoA racemase and its [2-H^3]Pristanoyl-CoA substrate, and determining the activity of the α-methylacyl-CoA racemase in the presence and absence of the competitive compounds and relating the effectiveness of the inhibitor compounds to inhibiting the activity of α-methylacyl-CoA racemase (Pg. 819, Column 1, Lines 18-22 and Column 2, Lines 1-11 and Table 4).

Schmitz teaches the use of the α-methylacyl CoA thioester (*R*)-2-methylteradecanoyl-CoA (Pg. 817, Table 1).

Claims 1, 2, 5 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmitz *et al.* (1994).

Schmitz teaches a screening method for determining the ability of various acyl-CoAs to inhibit the racemization of the α-methylacyl CoA thioester [2-H^3]Pristanoyl-CoA by isolated and purified rat liver α-methylacyl-CoA racemase, the various other CoAs acting as competitive inhibitors between the interaction of α-methylacyl-CoA racemase and its [2-H^3]Pristanoyl-CoA substrate, and determining the activity of the α-methylacyl-CoA racemase in the presence and absence of the competitive compounds and relating the effectiveness of the inhibitor compounds to inhibiting the activity of α-methylacyl-CoA racemase (Pg. 319, Column 1, Lines 11-32 and Pg. 320, Table 2).

Schmitz teaches a screening method for determining the ability of various chemical compounds to inhibit the racemization of the α-methylacyl CoA thioesters [2-H^3]Pristanoyl-CoA and [24,25-H^3]-trihydroxycoprostanoic acid (THCA) by isolated and purified rat liver α-methylacyl-CoA racemase, and determining the activity of the α-methylacyl-CoA racemase in the presence and absence of the competitive compounds and relating the effectiveness of the inhibitor compounds to inhibiting the activity of α-methylacyl-CoA racemase (Pg. 319, Column 1, Lines 33-43 and Column 2, Lines 25 and Pg. 320, Column 2, Lines 1-10 and Fig. 12 and Pg. 321, Table 3).

Schmitz teaches the use of the α-methylacyl CoA thioester (*R*)-2-methyltetradecanoyl-CoA (Pg. 317, Column 2, Lines 16-22 and Pg. 318, Fig. 5).

Claims 1, 3, 4, 7, 8, 11 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Richardson *et al.* (US 2002/0123081 A1).

Richardson teaches a method for screening compounds as candidate therapeutic agents for the treatment of prostate cancer by determining the ability of the compound to inhibit the expression of α-methylacyl-CoA racemase mRNA in a test sample by obtaining a test sample comprising prostate tumor cells (known in the art as having upregulated α-methylacyl-CoA racemase expression), exposing the test sample to a test compound, measuring the level of expression of α-methylacyl-CoA racemase mRNA in the test sample exposed to the test compound and determining that the test compound that the test compound is a candidate therapeutic agents for the treatment of prostate cancer if the level of expression of α-methylacyl-CoA racemase mRNA is less that a predetermined value in the test sample (Pg. 28, Claim 33), Richardson further teaches administering the identified candidate compound to a rodent harboring prostate cells or cells from a cancer resulting from metastasis of prostate cancer and determining whether the candidate compound reduces the proliferation of a prostate cancer (Pg. 29, Claim 57).

Richardson teaches the use of screening assays for evaluating the ability of a test compound or agent such as proteins, peptides, small molecules of other drugs) to modulate α-methylacyl-CoA racemase to its substrate (Pg.14, Column 2, [Paragraph 0144] and Pg.15, Paragraph [0150]).

Richardson teaches the use of the thioesters (R)-2-methyltetradecanoyl-CoA and (2R)-methylpentadecanoyl-CoA (Pg.8, Column 1, Lines 18-19 and 42-43).

Richardson teaches to determine the ability of a compound to influence the interaction of α-methylacyl-CoA racemase to its substrate and relating the activity thereof to the effectiveness of the compound to treating a disease (Pg. 14, Paragraph [0144]), and the activity is measured by measuring the amount of substrate (Pg.15, Paragraph [0150]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richardson *et al.* (US 2002/0123081 A1) in view of Schmitz *et al.* (1995).

The teachings of Richardson were discussed above.

Richardson does not teach a method to determine the ability of a compound to affect the interaction of α-methylacyl-CoA racemase and its ligand, a CoA thioester or an alpha-methylacyl fatty acid where the alpha carbon is an R-steroisomer, wherein the compound is selected from the group consisting of small organic compounds, proteins, carbohydrates and polynucleotides.

Richardson does not teach a method wherein the method comprises determining the amount or activity of α-methylacyl-CoA racemase resulting from the ability of the compound to influence the interaction of α-methylacyl-CoA racemase with its ligand and relating the amount or activity thereof to the effectiveness of the compound in the treatment or identification of a clinical or biological target for a disease, wherein the amount or activity is measured by measuring the amount of ligand.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the method for screening compounds as candidate therapeutic agents for the treatment of prostate cancer with the characterization of a compounds ability to influence the interaction α-methylacyl-CoA racemase with an R-stereoisomer α-methylacyl-CoA thioester, wherein the ability of a compound to influence the interaction of α-methylacyl-CoA racemase to its substrate is determined by measuring the substrate and relating the activity thereof to the effectiveness of the compound to treating a disease because these changes would allow one of ordinary skill in the art to further analyze the isolated effects of a test agent on the specific binding between α-methylacyl-CoA racemase and a specific isomer. This would allow one of ordinary skill in the art to narrowly focus on the effect of test compounds on the interactions between a specific enzyme and its ligand in the context of a disease system. There would have been a reasonable expectation of success because the method of Richardson fully teaches and suggests these modifications.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one with ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence or evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Martin
Examiner
Art Unit 1655

06/07/06

PATRICIA LEITH
PRIMARY EXAMINER